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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,533	07/11/2007	Stefan Rosewicz	833.1005	7738

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EXAMINER	
HADDAD, MAHER M	
ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/593,533	ROSEWICZ ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-36* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1.Applicant's amendment, filed on 09/19/2006, is acknowledged.

Claims 1-36 *are pending and being acted upon presently*

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

3. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-4 and 6-36, drawn to a method of treating or preventing a disease with impaired apoptosis of T-cells, macrophages and/or antigen-presenting cells, wherein the disease with impaired apoptosis of T-cells is autoimmune diseases, comprising administering galectin-2 to a patient in need thereof.

II. Claims 1-4 and 6-36, drawn to a method of treating or preventing a disease with impaired apoptosis of T-cells, macrophages and/or antigen-presenting cells, wherein the disease with impaired apoptosis of T-cells is autoimmune diseases, comprising administering a nucleic acid coding for galectin-2, or a complementary strand of a nucleic acid hybridizing to such coding nucleic acid (sense sequence), to a patient in need thereof.

III. Claims 1-4 and 6-36, drawn to a method of treating or preventing a disease with impaired apoptosis of T-cells, macrophages and/or antigen-presenting cells, wherein the disease with impaired apoptosis of T-cells is autoimmune diseases, comprising administering complementary strand of a nucleic acid coding for galectin-2, or a nucleic acid hybridizing to such coding nucleic acid (antisense sequence), to a patient in need thereof.

IV. Claims 1-4 and 6-36, drawn to a method of treating or preventing a disease with impaired apoptosis of T-cells, macrophages and/or antigen-presenting cells, wherein the disease with impaired apoptosis of T-cells is malignant T-cell diseases, comprising administering galectin-2 to a patient in need thereof.

V. Claims 1-4 and 6-36, drawn to a method of treating or preventing a disease with impaired apoptosis of T-cells, macrophages and/or antigen-presenting cells, wherein the disease with impaired apoptosis of T-cells is malignant T-cell diseases, comprising

administering a nucleic acid coding for galectin-2, or a complementary strand of a nucleic acid hybridizing to such coding nucleic acid (sense sequence), to a patient in need thereof.

VI. Claims 1-4 and 6-36, drawn to a method of treating or preventing a disease with impaired apoptosis of T-cells, macrophages and/or antigen-presenting cells, wherein the disease with impaired apoptosis of T-cells is malignant T-cell diseases, comprising administering complementary strand of a nucleic acid coding for galectin-2, or a nucleic acid hybridizing to such coding nucleic acid (antisense sequence), to a patient in need thereof.

VII. Claims 1-3, and 6-36, drawn to a method of treating or preventing organ rejection in a patient having undergone organ transplantation, in particular solid organ transplantation, comprising administering galectin-2 to a patient in need thereof.

VIII. Claims 1-3 and 6-36, drawn to a method of treating or preventing organ rejection in a patient having undergone organ transplantation, in particular solid organ transplantation, comprising administering a nucleic acid coding for galectin-2, or a complementary strand of a nucleic acid hybridizing to such coding nucleic acid (sense sequence), to a patient in need thereof.

IX. Claims 1-3 and 6-36, drawn to a method of treating or preventing organ rejection in a patient having undergone organ transplantation, in particular solid organ transplantation, comprising administering complementary strand of a nucleic acid coding for galectin-2, or a nucleic acid hybridizing to such coding nucleic acid (antisense sequence), to a patient in need thereof.

The inventions listed as Group I-IX do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical feature of the Group.

The specific technical feature of the Group 1 invention is a method of treating or preventing autoimmune diseases with galectin-2, while the specific technical feature of the Group 2 invention is the method of malignant T-cell diseases with galectin-2.

Since the special technical feature of the Group 1 invention is not present in the Groups II-IX claims and the special technical feature of the Group II-IX invention is not present in the Group 1 claims, unity of invention is lacking. Groups I-IX are different methods. Various methods of treating differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

Species Election

4. Irrespective of whichever group applicant may elect, applicant is further required under 35 US 121 (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

A. If any Group I-III is elected, applicant is required to elect a single specific autoimmune disease such as the one recited in claim 4 (each disease is a species). These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

B. If any Group I-IX is elected, applicant is required to elect a single specific combination therapy agent such as the agent recited in claims 10-22 (each combination agent is a species). Further, Applicant is required to elect a particular T-cell activator such as the one recited in claim 29. These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

5. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species,** including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under

37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

May 21, 2010

/Maher M. Haddad/
Primary Examiner,
Art Unit 1644